K132905

510(k) Summary

Submitter:	Arteriocyte Medical Systems, Inc. 45 South Street Hopkinton, MA 01748 USA
Contact Person:	Ann Charest Clinical and Regulatory Affairs Manager Phone: 508-497-8964 Fax: 508-497-8951 email: acharest@arteriocyte.com
Trade/Device Name:	200 Micron Blood Component Filter and Syringe Adapter
Regulation Number:	21 CFR 880.5440
Regulation Name:	Set, Blood Transfusion
Regulatory Class	II
Product Code:	BRZ
Common Name:	Fluid Reservoir and Delivery System
Predicate Device:	Charter Medical, Ltd: 150 Neonatal Syringe Set with 150 Micron Filter – K000685 Charter Medical, Ltd: Adult Blood Component Recipient Set with 150 Micron Filter – Pre-Amendment
Device Description:	Tubing assembly with a 200 micron filter connected by tubing with clamp and luer on one end and a purchased piston syringe on the other end.
Statement of Intended Use:	Indications for Use: The 200 Micron Blood Component Filter and Syringe Adapter is designed to filter clots and other particles from blood and blood components for delivery.
Substantial Equivalence Characteristics vs. Predicate:	The 200 Micron Blood Component Filter and Syringe Adapter is substantially equivalent to the noted predicate devices based on the similarities in material, technological characteristics, indications and test results.
Technological Characteristics	The proposed device is composed of the same material, has the same technological characteristics and is similar in design and function when compared to the predicate devices.

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Performance Testing	Results of the performance testing of the 200 Micron Blood Component Filter and Syringe Adapter established that the device is suitable for the intended use, to filter clots and other particles from blood and blood components for delivery and performs equivalently to Charter Medical, Ltd': 150 Micron Blood Component Recipient Sets.

ISO 10993-4 (2002), Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interaction with Blood, as amended 2006

ISO 10993-5 (2009), Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity

ISO 10993-10 (2010), Biological Evaluation of Medical Devices – Part 10: Tests for Irradiation and Skin Sensitization

ISO 10993-11 (2006), Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity Intracutaneuous injection test – ISO (P10-3866-00A)

ISO 10993-12 (2007), Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

ANSI/AAMI BF7: 2012, Blood Transfusion Filters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Arteriocyte Medical Systems Manager
Ms. Ann Charest
Clinical and Regulatory Affairs Manager
Pharmalink Technical Group
45 South Street
Hopkinton MA 01748

Re: K132905
Trade/Device Name: 200 Micron Blood Component Filter and Syringe Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: BRZ
Dated: September 23, 2013
Received: September 24, 2013

Dear Ms. Charest:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132905

Device Name: 200 Micron Blood Component Filter and Syringe Adapter

Indications for Use: The 200 Micron Blood Component Filter and Syringe Adapter is designed to filter clots and other particles from blood and blood components for delivery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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